AMENDMENTS

In the Claims:

Please cancel claims 28-41, 44-47 and 67 without prejudice.

REMARKS

Claims 28-41, 44-47 and 67 have been cancelled. Accordingly, claims 1-27, 42-43, and 48-66 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 441742000101. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

1. (Amended) A system for implanting a bypass graft, [including] comprising:

a tissue [dilating member having at its distal end a tissue dilating tip that converges in a distal direction] expansion device adapted to engage an orifice;

a tissue puncturing tool [supported within the dilating member and extending in the distal direction from the dilating tip, said tool] adapted to [puncture a tissue wall to] form an orifice enlargeable by the [dilating tip; and] expansion device;

a graft comprising a [substantially fluid impervious] graft wall with [first, second and third spaced apart regions of the wall having respective] first, second and third openings formed through the graft wall;

wherein the graft is adapted to be removably mounted on the [dilating member] expansion device in which the [dilating member] expansion device extends through the first and third openings, with the first opening disposed near [the dilating tip] a distal end of the expansion device and the third opening disposed proximally of the first opening so to enable use of the [dilating member to insert] expansion device to position the first region of the graft wall into engagement with a first orifice in [the] a tissue wall for fixation of the first region therein; and

wherein the graft further is [slideable] slidable relative to the [dilating member] expansion device to permit a proximal withdrawal of the [dilating member] expansion device from the first region after said fixation[, and further to allow an insertion of the dilating member into the second opening for securing the second region of the graft wall within a second orifice in the tissue wall whereby the graft provides a fluid flow conduit between the first orifice and the second orifice]; and

a closure mechanism for closing the third opening[,] following withdrawal of the [dilating member] expansion device from the graft.

2. (Amended) The system of claim 1 further including [first and second] a fixation [elements] element near the first [and second ends, respectively] end.

3. (Amended) The system of claim 2 wherein the fixation [elements incorporate features for] element is adapted to mechanically [securing the graft ends] secure the first region of the graft wall to the tissue wall.

4. (Amended) The system of claim 2 wherein [at least one of] the fixation [elements] element comprises an electrically conductive heating element.

5. (Amended) The system of claim [2 further comprising] 1 wherein the expansion device comprises an expandable balloon [mounted to the dilating] member.

6. (Amended) The system of claim 1 wherein said closure mechanism comprises a [string or thread element] suture disposed through [the graft material] at least a portion of the graft wall around the third opening.

7. (Amended) The system of claim 1 wherein said tissue puncturing tool comprises an elongate needle mounted [slideably] slidably within the [dilating member] expansion device.

8. (Amended) A system for deploying a bypass graft, comprising:

an elongate and flexible carrier having a proximal end and a distal end, insertable by the distal end for intralumenal movement toward a selected site along a body lumen [while the proximal end remains outside of the body];

a tissue perforating mechanism proximate the distal end, positionable at a first location near the selected site and operable from the proximal end of the carrier to form a first opening through tissue at the first location, and further positionable at a

second location near the selected site and operable to form a second opening through tissue at the second location;

a graft guide supported by the carrier and disposed near said distal end and movable into a guiding position in which the graft guide extends from the first location through the first opening to the second location and through the second opening;

a tubular graft adapted [to be mounted to the carrier] for movement along the carrier; and

a graft controller operable to move the graft, when so mounted, distally along the carrier toward the graft guide and distally along the graft guide when the guide is in the guiding position to a bypass location in which the graft extends from the first location to the second location and further extends through the first and second openings.

10. (Amended) The system of claim 9 wherein the graft guide comprises a dilator [slideably] slidably contained in the catheter lumen and having a tapered distal tip, and wherein the tissue perforating mechanism comprises [said tip and] an elongate needle slideably contained within the dilator.

12. (Amended) The system of claim 10 wherein the dilator distal tip is pre-shaped [in a distal region, including the distal tip,] to facilitate selective positioning of the tip by rotating the dilator.

13. (Amended) The system of claim 10 further comprising a needle stop [for limiting an extent of penetration of the needle into tissue].

14. (Amended) The system of claim 10 wherein the graft controller comprises an elongate, tubular stylet insertable within the catheter lumen.

15. (Amended) The system of claim 9 wherein the graft guide comprises a distal [end] region of the catheter[,] and the tissue perforating mechanism comprises (i) a dilator having a tapered distal tip, said dilator contained [slideably] slidably within the catheter lumen, and (ii) an elongate needle contained [slideably] slidably within the dilator.

17. (Amended) The system of claim [9] 8 further comprising a collet [fixation element to secure the graft at least at the second location].

20. (Amended) A process for translumenally deploying a bypass graft, comprising:

advancing an elongate catheter intralumenally toward a selected site along a body lumen;

[with a distal end of the catheter near the selected site,] forming a first opening through a first area of tissue wall defining the [body] lumen via a tissue perforating mechanism [mounted near a distal end of the catheter];

advancing the tissue perforating mechanism through the first opening to a location spaced apart from the first opening; [opening, then using the mechanism to form]

forming a second opening through a second area of tissue wall at said location with said mechanism;

advancing a graft guide distally through the first opening to said location and [then] through the second opening;

[with the graft guide so positioned,] advancing a tubular graft along the guide via a graft controller to a bypass position [location] in which the graft extends [from] through the first opening to the second opening [and through the first and second openings, forming a bypass conduit in fluid communication with the body lumen; and

while maintaining the graft in said bypass position, proximally withdrawing the catheter, the tissue perforation mechanism and the graft guide].

21. (Amended) The process of claim 20 wherein the graft guide comprises a tissue dilator [slideably] slidably mounted within the catheter[, and the step of advancing the graft guide comprises distally advancing the dilator relative to the catheter].

23. (Amended) The process of claim 20 further comprising the step of securing the graft at proximal and distal end portions thereof to tissue at the first and second openings, respectively[, with the graft at the bypass location].

24. (Amended) The process of claim 23 wherein at least one of the first and second openings is formed through tissue of an organ defining a cavity, and whereby the graft, when secured, is [open to the cavity] in fluid communication with the cavity.

25. (Amended) The process of claim 23 wherein said first and second openings are formed through tissue walls of a first [different] blood [vessels,] vessel and a second blood vessel, respectively, and whereby the graft, when secured, provides a fluid conduit [fluid] coupling the [two different vessels] first and second blood vessels.

26. (Amended) The process of claim 20 wherein at least one of the openings is through an organ tissue wall into [to] a cavity of [the] an organ.

27. (Amended) The process of claim 20 wherein the first and second openings are formed through tissue walls of [two different blood vessels] a first blood vessel and a second blood vessel, respectively.

42. (Amended) An anastomotic connector comprising:

at least one encircling member having a distal end attachable to [the] a graft, a proximal end attachable to the graft and configured to expand into and contact the interior of a vessel or organ wall.

57. (Amended) The system of claim 53 wherein at least one of the first connector and the second connector comprises at least one substantially annular member adapted to compress for insertion through the delivery mechanism and expand into contact with at least a portion of the vessel upon advancing beyond [and] an end of the delivery mechanism.

62. (Amended) The system of claim 61 further comprising a stylet adapted to advance one or both of said first and second connectors [and said tubular member] through one or both of said first opening or second opening, respectively.

64. (Amended) A method for creating an anastomosis between a tubular member and a mammalian vessel or organ segment, comprising:

positioning an end of the tubular member having a self-expanding connector attached thereto near the mammalian vessel or organ segment;

[penetrating] creating an opening within a wall of the vessel or organ segment [to create an opening in said wall]; and

expanding the opening and advancing a distal portion of the connector through said opening such that the distal portion enters an interior of said vessel or organ segment and self-expands into an expanded configuration and the distal portion directly contacts an inner surface of the vessel or organ segment wall without further penetrating the wall.

Please add the following new claims:

--68. (New) The system of claim 1 wherein the expansion device comprises a dilator having a tissue dilating tip at its distal end.

69. (New) The system of claim 1 wherein the graft is slidable relative to the expansion device to further allow fixation of the second region of the graft wall into engagement with the second orifice in the tissue wall.

70. (New) The system of claim 69 wherein fixation of the second region of the graft wall into engagement with the second orifice occurs prior to fixation of the first region of the graft wall into engagement with the first orifice.

71. (New) The system of claim 1 wherein said closure mechanism comprises a staple disposed through at least a portion of the graft wall around the third opening.

72. (New) An implantable anastomosis bypass graft system comprising:

a tubular graft comprising a first end and a second end with a lumen defined therebetween, at least one of the first end and the second end of the tubular graft being positionable at a location along a body lumen via a proximal attractive element; and

a distal attractive element disposable within the body lumen and adapted to magnetically engage the proximal attractive element such that an orifice is formed at the location along the body lumen whereby the tubular graft is in fluid communication with the body lumen.

73. (New) The system of claim 72 further comprising an elongate and flexible carrier having a proximal end and a distal end, insertable by the distal end for intralumenal movement toward a selected site along the body lumen.

74. (New) The system of claim 73 further comprising a tissue perforating mechanism proximate the distal end of the carrier, positionable at a first location near the selected site and operable from the proximal end of the carrier to form a first opening through tissue at the first

location, and further positionable at the location along the body lumen and operable to form the orifice through tissue at the location along the body lumen.

75. (New) The system of claim 74 further comprising a graft guide supported by the carrier and disposed near the distal end and movable into a guiding position in which the graft guide extends from the first location through the first opening to the location along the body lumen and through the orifice.

76. (New) The system of claim 75 further comprising a graft controller operable to move the graft, when so mounted, distally along the carrier toward the graft guide and distally along the graft guide when the guide is in the guiding position to a bypass location in which the graft extends from the first location to the location along the body lumen and further extends through the first opening and through the orifice.

77. (New) The system of claim 73 wherein the carrier comprises a catheter having a catheter lumen formed therethrough.

78. (New) The system of claim 74 wherein the tissue perforating mechanism comprises an elongate needle slideably contained within the carrier.

79. (New) The system of claim 78 further comprising a needle stop.

80. (New) The system of claim 75 wherein the graft guide comprises a dilator slideably contained in the carrier and having a tapered distal tip.

81. (New) The system of claim 80 wherein the dilator distal tip is pre-shaped to facilitate selective positioning of the tip by rotating the dilator.

attaching an end of a tubular graft to the second opening such that the tubular graft and the body lumen are in communication.

89. (New) The method of claim 88 further comprising advancing an elongate catheter intralumenally toward a selected site along the body lumen prior to forming the first opening through the tissue wall.

90. (New) The method of claim 88 wherein prior to engaging the tissue wall at the location spaced apart from the first opening, the method further comprises:

advancing the tissue perforating mechanism through the first opening to the location spaced apart from the first opening; and

positioning the tissue perforating mechanism over the location via a magnetic force exerted on the mechanism.

91. (New) The method of claim 88 further comprising advancing a graft guide distally through the first opening to said location and through the second opening prior to attaching the end of the tubular graft to the second opening.

92. (New) The method of claim 91 further comprising advancing the tubular graft along the guide via a graft controller to a bypass position in which the graft extends through the first opening to the second opening prior to attaching the end of the tubular graft to the second opening.

93. (New) The method of claim 91 wherein the graft guide comprises a tissue dilator slideably mounted within the catheter.

94. (New) The method of claim 91 wherein said graft guide comprises a distal region of the catheter, and the step of advancing the graft guide comprises distally advancing the catheter until the distal region of the catheter extends through the first and second openings.

95. (New) The method of claim 88 wherein the first and second openings are formed through tissue walls of a first blood vessel and a second blood vessel, respectively, and whereby the graft, when secured, provides a fluid conduit coupling the first and second blood vessels.

96. (New) The method of claim 88 wherein at least one of the openings is through an organ tissue wall into a cavity of an organ.

97. (New) The method of claim 88 further comprising positioning the distal attractive element at the location within the body lumen.

98. (New) The method of claim 88 wherein the distal attractive comprises a metallic guidewire.

99. (New) The method of claim 98 wherein the metallic guidewire further comprises a magnet.

100. (New) The method of claim 99 wherein the magnet is disposed at a distal end of the guidewire.

101. (New) The method of claim 88 wherein the proximal attractive element is disposed on the mechanism and exerts a magnetic force on the distal attractive element.

102. (New) The method of claim 101 wherein the proximal attractive element is comprised of a ferrous material.

103. (New) The method of claim 102 wherein the proximal attractive element is an electromagnet comprised of at least one conductive coil.

104. (New) An anastomosis connector for connecting a tubular graft to a blood vessel or hollow body organ comprising:

at least one compressible member having a first segment and a second segment,

the first segment being configured to engage a first portion of interior surface of the vessel or organ,

the second segment being configured to engage a second portion of interior surface of the vessel or organ, a distal end of the second segment being attached to a distal end of the first segment,

the compressible member being radially deformable between a first reduced profile and a second expanded profile.

105. (New) The connector of claim 104 further comprising a plurality of additional compressible members, each of the additional compressible members being radially deformable between the first reduced profile and the second expanded profile.

106. (New) The connector of claim 104 wherein the compressible member is joined by a proximal end of the member to the tubular graft.

107. (New) The connector of claim 104 wherein the compressible member expands from the first reduced profile to the second expanded profile upon removal of a constraining force.

108. (New) The connector of claim 107 wherein a catheter surrounding the compressible member provides the constraining force.

109. (New) The connector of claim 104 wherein the compressible member is radially self-expanding from the first reduced profile and the second expanded profile.

110. (New) The connector of claim 104 wherein the compressible member is comprised of a memory elastic material.

111. (New) The connector of claim 110 wherein the memory elastic material is selected from the group consisting of stainless steel, nickel titanium, and thermoset plastic.

112. (New) The connector of claim 104 wherein the expanded profile of the compressible member defines a radially enlarged profile.

113. (New) The connector of claim 112 wherein the radially enlarged profile is substantially circular.

114. (New) The connector of claim 104 wherein the expanded profile of the compressible member is configured to conform to the interior surface of the vessel or organ.--